K092389

5. 510(k) Summary

1. Company Identification

OCT 13 2009

SUZUKEN CO, LTD.
8 Higashikataha-machi, Higashi Nagoya, Aichi, JAPAN 46191
Tel: +81-52-950-6327
Fax: +81-52-950-7440

2. Official Correspondent

Motokazu Takeuchi (Mr.)
Senior Manager

3. Date of Submission

August 4, 2009

4. Device Trade name

Disposal ECG electrodes, Model Easyrode

5. Common/Usual Name

Electrocardiograph Electrode

6. Classification Number

Electrocardiograph Electrode classified in Class II per 21 CFR 870.2360, DRX

7. Predicate Device

Manufacturer	:	3M Health Care
Device Name	:	3M Red Dot 2560 Monitoring Electrode with Foam Tape and Stickey Gel
510(k) No.	:	K970796

8. Description of the Device

Easyrode is a self-adhesive, non-sterile, single use disposable electorode which includes a silver/silver chloride sensing element and conductive gel.
These electrodes include a pressure sentive adhesive non-woven tape which hold the conductive elements of the electrodes in place on the patient's skin for short or long term ECG procedures.

9. Intended Use

The Easyrode is intended for use in ECG Monitoring. The Easyrode can be used in all ECG applications where standard ECG monitoring electrodes are used. This electrode can be used for short term and long term (2 Days) monitoring.

10. Technological Characteristics

Intended for Use
Easyrode: Used for short time and long time (up to 2day)
Predicate device: Used for short time and long time (2day)

Easyrode is used for 2day and below.

Material:
Easyrode: Non-woven tape
Predicate device: Foam tape

Non-woven is allow air pass through easily than foam.
That means non-woven is more adhesive to patient skin

Comparison table of the principal characteristics of 2 devices is shown in the *9. Substantial Equivalence Discussions*.

11. Conclusion

The results of these measurements demonstrated that the Easyrode is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 26 2011

Suzuken Co., Ltd
c/o Mr. Koji Kubo
Cosmos Corporation
3F, 2-17-6 Akebono-cho
Tachikawa-shi, Tokyo 190-0012
JAPAN

Re: K092389
Trade/Device Name: Disposal ECG Electrodes, Model Easyrode
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph electrode
Regulatory Class: II (two)
Product Code: DRX
Dated: July 31, 2009
Received: August 5, 2009

Dear Mr. Kubo:

This letter corrects our substantially equivalent letter of October 13, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known) K092389

Device Name: Disposal ECG electrodes, Model Easyrode

Indications For Use :

The Easyrode is intended for use in ECG Monitoring. The Easyrode can be used in all ECG applications where standard ECG monitoring electrodes are used. This electrode can be used for short term and long term (2 Days) monitoring.

Prescription Use__X__ AND / OR Over-The Counter Use _____

(Per 21 CFR 801.109 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092389